K113352

APR 16 2012

510(k) Summary

Pursuant to 21 CFR 807.92c

Submitted By: Andrew Rodenhouse
Transcorp, Inc.
1000 100th St. SW Suite F
Byron Center, MI 49315
Ph: 616-855-5375
Fax: 616-877-4522

Date: March 29, 2012

Device Information:

Trade Name: Transcorp Spinal Access System

Common Name: Rigid Endoscope and Instrument Set

Classification: 21 CFR Section 888.1100, Arthroscope Product Code: HRX

Substantially Equivalent Device:

K032891: TranS1 Trans-Sacral Spinal Access and Preparation Device

Device Description:

The Transcorp Spinal Access System is an instrument system used for minimally invasive visualization and access to the anterior spine. The system includes the following components:

- Left and right orientation guides with 5°-15° of angulation
- Fixation pins, 12-16mm
- Drills, 2-6mm Diameter x 10-18mm Depth
- Cannulated Drills, 2-6mm Diameter x 10-18mm Depth
- Guide Pin Adapter

- Guide Pins
- Quick Disconnect Handle
- Fixation Pin Driver
- Tamp
- Mallet

Intended Use:

The Transcorp Spinal Access System is indicated for minimally invasive visualization and access to the anterior spine for assisting in various surgical procedures such as herniated disc repair, biopsy, or harvesting autogenous bone.

Comparison to Predicate:

The Transcorp Spinal Access System and the predicate device include similar stainless steel instruments used in accessing the spine. The Transcorp Spinal Access Systems shares the same technological characteristics including the types of instruments included, the material, and the function as the predicate system.

Summary of Non Clinical Testing:

Cadaver performance testing, functional testing, and comparison to the predicate demonstrated that the Transcorp Spinal Access System can be used in accordance with the Indications for Use.

Conclusion

Nonclinical tests demonstrate that the Transcorp Spinal Access System is as safe, as effective, and performs at least as safely and effectively as the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Transcorp, Inc.
% Mr. Andrew Rodenhouse
1000 100th Street SW, Suite F
Byron Center, Michigan 49315

APR 16 2012

Re: K113352
Trade/Device Name: Transcorp Spinal Access System
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: II
Product Code: HRX
Dated: March 30, 2012
Received: March 30, 2012

Dear Mr. Rodenhouse:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K113352

Device Name: Transcorp Spinal Access System

Indications for Use:

The Transcorp Spinal Access System is indicated for minimally invasive visualization and access to the anterior spine for assisting in various surgical procedures such as herniated disc repair, biopsy, and harvesting autogenous bone.

Prescription Use X or Over-the-counter use _____
(per CFR 801.109)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden for mxm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113352